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May 22, 2003

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)  
5100 Paint Branch Parkway  
College Park, Maryland 20740  
Reference phone #301-436-2373

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) **Name of Address of distributor:**  
Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035
- (2) **Text of the statement(s):**  
• Lycopene is a potent serum antioxidant carotenoid that also concentrates in prostate tissue. • Saw Palmetto Berry Extract (*Serenoa repens*) is standardized to 85-95% fatty acids and sterols such as B-sitosterol, lupeol, campesterol, cycloartenol, farnesol and phytol. • DHA & EPA Omega 3 from molecular distilled fish oil are essential fatty acid modifiers of prostaglandins which contribute to prostate health. • Cernitin Pollen Extract contains various water, and fat soluble components from plant pollen and is identical to the form utilized in clinical trials to improve bladder function and urinary flow. • Green Tea Extract promotes circulation and contains potent free radical scavenging flavonoids known as catechins.
- (3) **Name of the dietary ingredient(s) if not provided in the text of the statement:**  
Saw Palmetto (*Serenoa repens*)(85-95% Fatty acids and sterols) • Lycopene (GMO-free tomato extract) • Fish Oil (Molecular distilled) [DHA (Docosahexaenoic Acid), EPA (Eicosapentaenoic Acid), Stearidonic Acid] • Stinging Nettle Extract (*Urtica dioica*) • Cernitin Pollen Extract • Green Tea Extract (*Camellia sinensis*)(40% Polyphenols) • Lecithin (35% Phosphatidylcholine) • Gamma Tocopherol
- (4) **Name of the dietary supplement(s)**  
Prostate Optimizer™ 60 softgels
- (5) **The following disclaimer appears on the label in bold:**  
These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,

  
Siddharth Shastri  
Vice President, Product Development

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